GE Healthcare

Pete McCabe
President and CEO
GE Healthcare, Surgery
384 Wright Brothers Drive
Salt Lake City, Utah 84116
U.S.A.
Pete.mccabe@med.ge.com

Certified Mail Return Receipt Requested

URGENT RECALL NOTICE

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVENT SYSTEM(S) OF THESE ISSUES AND HOW TO ADDRESS THEM

February 21 2007

To: **Hospital Administrator**
Director/Manager of Radiology

Subject: **Product Safety Issues**

Affected Products: **OEC UroView 2800, OEC 9800 Plus Digital, OEC MiniView 6800, OEC FlexiView 8800 Mobile C-Arm**

Our records indicate that your facility has one or more of the following GE Healthcare OEC (GEHC OEC) devices that has received a replacement hard disk drive:

- OEC UroView 2800
- OEC 9800 Plus Digital
- OEC MiniView 6800
- OEC FlexiView 8800 Mobile C-Arm

GEHC OEC has discovered an issue with the hard disk drives that were installed on the above listed products during service calls. The manufacture dates of the affected hard disk drives are between October 15, 2004 and December 8, 2004

This issue could potentially result in the system failing to store images when the hard disk drive capacity exceeds 170 images instead of the expected 400 images. Systems may also fail to boot or lose patient data as this image capacity is approached.

DOC0287403

Your GEHC OEC Field Service Engineer will be contacting your facility to arrange to have a replacement hard disk drive installed on your system.

Until a GEHC OEC Field Service Engineer has replaced the hard disk drive users should ensure that images on the hard disk drive are stored via an alternate permanent media (film, long term storage) as the hard disk drive approaches the 170 image capacity.

GEHC OEC is actively working to replace the affected hard disk drives in a timely manner. GEHC OEC will, without charge, remedy this issue.

If you have any questions or concerns regarding these issues, please do not hesitate to contact the service team for further information at 800-874-7378 option 8. Information is available at this number 24 hours per day, 7 days a week.

Thank you,

Pete McCabe
President and CEO

GE Healthcare

Important Device Removal & Product Safety Alert

06 February 2006

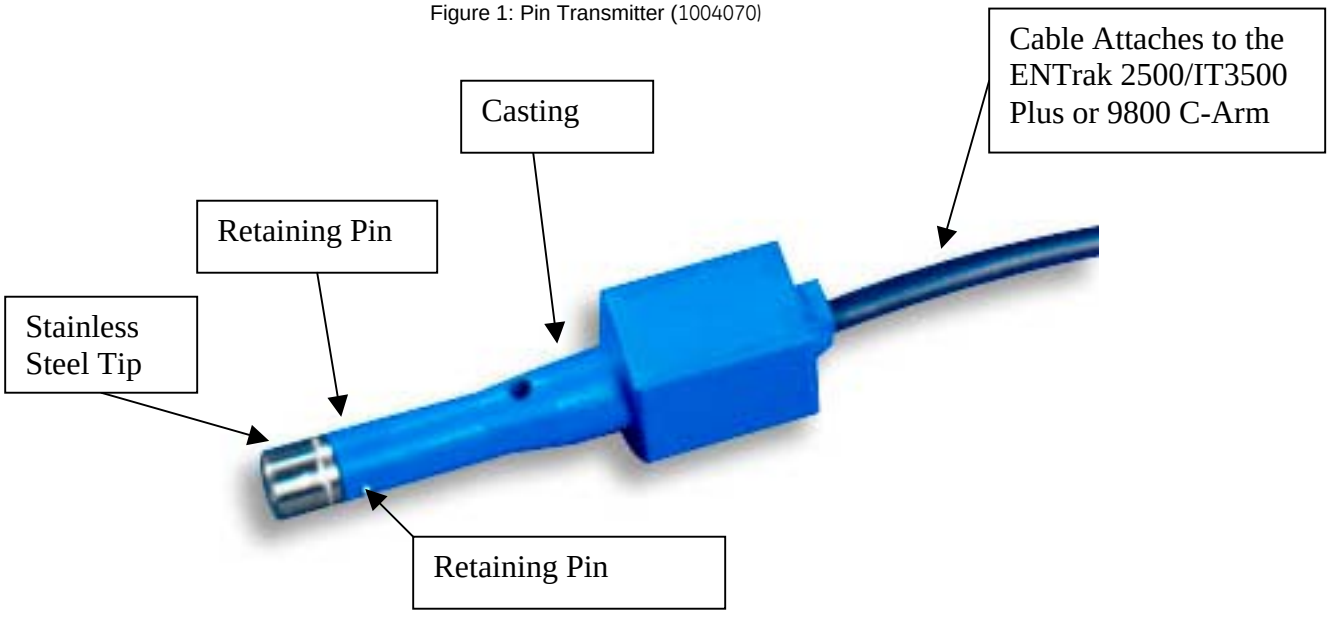
Director of Surgical Services
TBD – Hospital Name and address
TBD – Hospital Name and Address
TBD – Hospital Name and Address

Dear Healthcare Provider,

It has come to our attention that there is a potential safety concern associated with the GE Healthcare Navigation Pin Transmitter (GE P/N 1004070) that you might own. Because patient safety is of paramount concern to GE, we ask your immediate attention to help us resolve this matter.

GE Healthcare Navigation Pin Transmitter. (PN: 1004070) [See Figure 1 Below]

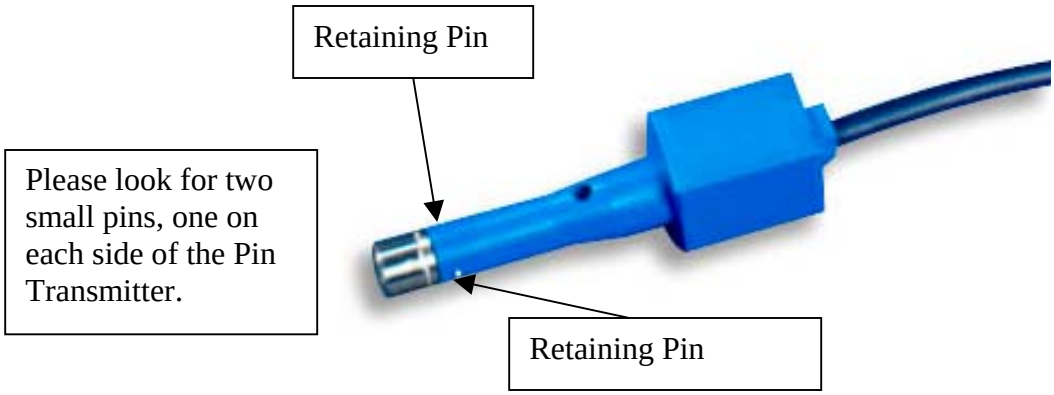
Figure 1: Pin Transmitter (1004070)



The housing of the Pin transmitter consists of two main parts: the casting (plastic) and the stainless steel tip that attaches the housing to the clamp/pin which is affixed to the patient (See Figure 1). The design is intended to have a small pin through each side wall of the casting to secure the stainless steel tip with two pins. In a few cases, we have seen that the stainless steel tip of the Pin Transmitter has disconnected from the casting because only one pin of the transmitter was secured. In these cases, there is a potential for this small, unattached retaining pin to fall into the surgical field.

GE Healthcare

Figure 2: Pin Transmitter (1004070)



Please perform a visual inspection of your GE Healthcare Surgical Navigation Pin Transmitter (PN: 1004070) to make sure that your Pin Transmitter is pinned on both sides of the transmitter (See Figure 2) and follow the instructions below:

If you have a defective Pin Transmitter (pin on one side only):

1) Please discontinue the use of the Pin Transmitter and contact GE Healthcare Customer Service at (800) 874-7378 option 1 to arrange for a part replacement. You may fill out the attached form and FAX it to GE Healthcare Customer Service to help expedite the replacement of the Pin Transmitter.
2) Please convey this information to your OR management along with all users of the ENTrak 2500 Plus, InstaTrak 3500 Plus, or 9800 C-Arm Navigation Systems.

If your Pin Transmitter is not defective (pinned on both sides), you may continue to safely use this device. We simply ask that you contact GE Healthcare Customer Service at (800) 874-7378 option 1 and confirm your inspection with us. You may fill out the attached form and fax it back to GE Healthcare Customer Service at your first available opportunity.

If you have an affected Pin Transmitter, we plan to replace it as soon as possible at no cost to you. A GE Surgery Field Service Engineer will be contacting you to arrange for a part replacement which will enable you to continue using your ENTrak 2500 Plus, IT 3500 Plus and 9800 C-Arm Navigation Systems.

GE appreciates your awareness and cooperation in order to remedy this potential health concern. If you have any questions please contact GE Healthcare Customer Service at (800) 874-7378 option 1.

Sincerely,

Kenneth F. Miles, Ph.D.

Kenneth F. Miles, Ph.D.
GE Healthcare - Interventional Cardiology & Surgery
V.P. Quality & Regulatory

GE Healthcare

Pin Transmitter Request Form

Facility:

Contact:

Part Replacement: GE Healthcare Surgical Navigation Pin Transmitter (PN: 1004070)

Please select **one** of the following:

☐ I have inspected my GE Healthcare Surgical Navigation Pin Transmitter (PN: 1004070) and it **does require** replacement.

☐ I have inspected my GE Healthcare Surgical Navigation Pin Transmitter (PN: 1004070) and it **does NOT** require replacement.

Printed Name: _____

Date: _____

Please FAX to: (801) 521-3903

IMPORTANT DEVICE REMOVAL & PRODUCT ALERT

GE Healthcare
OEC Medical Systems, Inc.

Kenneth F. Miles, PhD
Vice President Quality Assurance
and Regulatory Affairs

384 Wright Bros. Drive
Salt Lake City, UT 84116-2862

T 801-536-4730
F 801-517-6459
Kenneth F. Miles@ge.com

May 31, 2006
<TBD – Hospital Name and address>
<TBD – Hospital Name and Address>
<TBD – Hospital Name and Address>

Dear Health Care Provider,

It has come to our attention that there is a potential concern associated with the GE Healthcare Navigation Anterior Cervical Post (GE P/N 1006385 or 1006385-NAV an accessory used with the InstaTrak 3500 Plus and 9800 C-Arm Navigation Systems. Because the quality of our products is of paramount concern to GE, we request your immediate attention to help us resolve this matter.

The weld between the post body and the screw was not properly formed in several devices, and the weld can fail even when minimal force is used. Our concern is that if this occurs the screw might have to be removed from the bone by other means and that the scheduled procedure could not continue.

According to our records, your facility purchased this product either in a kit or separately. We will replace it as soon as the product is available at no cost to you. This notification applies to all GE Anterior Cervical Posts (GE P/N 1006385) in commercial distribution and is not limited to any specific lot number. This issue does not affect the GE Healthcare Posterior Threaded Bone Pin (GE PN 1003997).

4" Anterior Cervical Post – Actual Size

Please do the following to facilitate this removal:

1. **Identify and discontinue using this product (GE P/N 1006385 or 1006385-NAV)**
2. **Complete and return attached form**
3. **Communicate this information to your OR Staff and users of the InstaTrak 3500 Plus, or 9800 C-Arm Navigation Systems.**

GE appreciates your awareness and cooperation in order to remedy this potential health concern. Call GE Healthcare Customer Service at (800) 874-7378 Option 1 if you have additional questions.

Sincerely yours,

Kenneth F. Miles, Ph.D.

Kenneth F. Miles, Ph.D.
GE Healthcare - Interventional Cardiology & Surgery
Vice President Quality Assurance and Regulatory Affairs

VERIFICATION OF PRODUCT DISPOSITION

To **Eric Russell, GE Healthcare** **FAX** **801-206-0003**

From _____
PRINTED NAME

Date _____

Subject **4" Anterior Cervical Post Navigation** **Page 1 of ____**

<TBD – Hospital Name and address>
<TBD – Hospital Name and Address>
<TBD – Hospital Name and Address>

Please verify the disposition of your four-Inch Anterior Cervical Post (GE P/N 1006385 or 1006385-NAV) by marking the applicable box.

☐ I have removed my cervical post(s) from service. Please credit my account

☐ I have removed my cervical post(s) from service. Please replace it when available

☐ I do not have this instrument

Name _____
SIGNATURE

Name change?

New facility Name _____

Address _____

City _____ State _____ Zip _____

Email option: Scan and send completed form to: Sydnee.McMillan@ge.com Subject Line "Cervical Post"

GE Healthcare
OEC Medical Systems, Inc.
384 Wright Bros. Drive
Salt Lake City, Utah 84116
Phone: 801-328-9300
Fax: 801-328-4300

IMPORTANT RADIATION SAFETY NOTICE – 9800 PRODUCT

Date: August 14, 2006

To: Facility Administrator or Radiation Safety Officer

GE Healthcare recently learned that your 9800 C-Arm might exceed the 20 R/minute limit required by the Code of Federal Regulations when in High Level Fluoro (HLF) Pulsed Mode and may pose a serious radiation hazard to the both patient and staff. This could occur if the Default Pulse Rate is set to 30 PPS on the 9800 C-Arm. Only a Field Service or Biomedical Engineer can manually change this value using RUS (Remote Utility Suite Software) or RUT (Remote Utility Tool). The user cannot select it.

Please do the following steps to determine if this issue affects your system:

1. Power the system up.
2. Press the PULSE button on the C-Arm.
3. If 30 PPS is displayed in the status bar on the right workstation monitor, the Default Pulse Rate is set to 30 PPS.
4. If 30 PPS is displayed **PLEASE IMMEDIATELY DISCONTINUE any use of the High Level Fluoro Pulsed mode** and contact your service team at 800-874-7378 for a priority service visit to correct this problem.

If 30 PPS is NOT displayed your system complies with the Code of Federal Regulations, however, a GE OEC Field Service Engineer will contact you via phone and determine if a service call is required to check your system.

GE Healthcare will, without charge, remedy the defect or bring the product into compliance with each applicable federal standard. This product correction is being conducted according to Field Modification Instruction 15045.

For Further information, please contact your service team at 800-874-7378.

Sincerely yours,

Kenneth F. Miles, Ph.D.

Kenneth F. Miles, PhD.
Vice President Quality & Regulatory Affairs
GE OEC Medical Systems, Inc.

GE Healthcare

Pete McCabe
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URGENT RECALL NOTICE

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVENT SYSTEM(S) OF THESE ISSUES AND HOW TO ADDRESS THEM

November 8, 2006

To: **Hospital Administrator**
Director/Manager of Radiology

Subject: **Product Safety Issues**

Affected Products: **FlexiView 8800 Mobile C-Arm, OEC® UroView 2800, OEC® 9800, OEC® FluoroTrak 9800 Plus, OEC® 9800 Plus, OEC® 9800*MD* Motorized C-arm System, and OEC® Miniview 6800**

Our records indicate that your facility has one or more of the following GEHC OEC products:

- FlexiView 8800 Mobile C-Arm
- OEC® Miniview 6800
- OEC® UroView 2800
- OEC® 9800
- OEC® FluoroTrak 9800 Plus
- OEC® 9800 Plus
- OEC® 9800*MD* Motorized C-arm System

GE Healthcare has identified several intermittent potential safety issues that may occur with these products based upon feedback from some customers. The details and symptoms of these issues, as well as the associated interim or permanent solutions, are outlined below.

1. Navigation Tracking Inaccuracy:

Affected Products: OEC® FluoroTrak 9800 Plus

An issue has been discovered with the OEC® FluoroTrak 9800 Plus that could result in an incorrect position of instrumentation versus the displayed reference image. **This issue could result in an injury to the patient due to incorrect anatomical location of an instrument during a procedure.**

Permanent Solution:

GE OEC is currently investigating corrective solutions. When a corrective solution has been identified the GE OEC service team will contact your facility and arrange implementation of the corrective action.

Users are advised to stop using the system WITH NAVIGATION until this replacement has been successfully completed. OEC® FluoroTrak 9800 Plus system may be used as a standard C-Arm providing you review the other issues as listed below.

2. System Lock Up:

Affected Products: FlexiView 8800 Mobile C-Arm, OEC® UroView 2800OEC® 9800OEC® FluoroTrak 9800 PlusOEC® 9800 Plus, OEC® 9800*MD* Motorized C-arm System

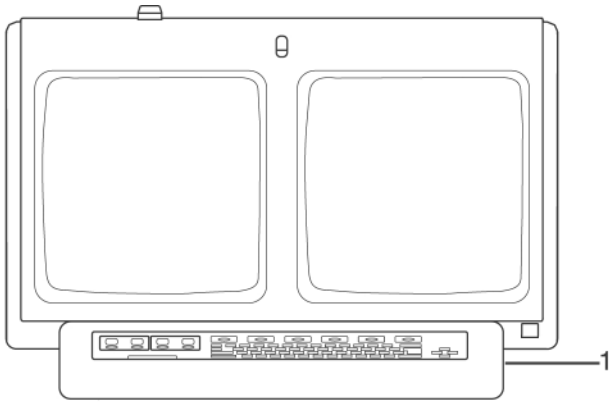
GEHC OEC has become aware of a potential problem with the above-indicated products where the C-arm may lock-up. Specifically, during system usage, the system may fail to function (produce live x-rays), and the collimators may close. In addition, the system display may indicate that the system is active (such as sound and/or light displays) when, in fact, the system is not producing live x-rays. The left monitor of the system will not update (no live fluoroscopy). There will be no radiation emission occurring despite the audible and visual indicators. If it is suspected that the system has emitted an uncommanded radiation exposure the user should contact GEHC to have the exposure logs reviewed to confirm if an exposure was made.

In critical clinical scenarios in which the C-arm is being used to make real-time therapeutic decisions or guide real-time interventions, a system lock-up may cause a procedural delay. Users should always be certain that the images shown on the Left Monitor are refreshing and are in fact live x-ray images (one indicator of this status is that the word "live" displayed on the screen).

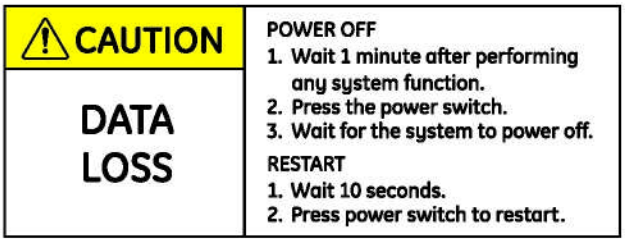
Interim Solution:

Should your OEC System experience a Lock-up, restarting (rebooting) the system should restore system functionality. The restarting (reboot) procedure for OEC 9800 Plus, OEC Flexiview 8800, and OEC UroView 2800 will take less than 3 minutes. **Images saved prior to the system locking up will be restored and are retrievable. Images not saved prior to the system failure will not be restored.** At this time a corrective solution for the OEC 9800 Plus, OEC Flexiview 8800, and OEC UroView 2800 is under investigation. Your facility will be notified as soon as a solution has been identified.

Instructions for rebooting (restarting) the system are located in the Operators Guide. **In addition enclosed is a sheet of supplemental stickers, including instruction for attachment, which demonstrates the restart steps. These stickers should be promptly attached to your system(s)as indicated below (suggest placement in location #1).**



SUGGESTED PLACEMENT OF STICKER ON SYSTEM


CAUTION
DATA LOSS
POWER OFF
1. Wait 1 minute after performing any system function.
2. Press the power switch.
3. Wait for the system to power off.
RESTART
1. Wait 10 seconds.
2. Press power switch to restart.

3. Incorrect Image Display:

Affected Products: FlexiView 8800 Mobile C-Arm, OEC® UroView 2800OEC® 9800OEC® FluoroTrak 9800 PlusOEC® 9800 Plus, OEC® 9800*MD* Motorized C-arm System, OEC® Miniview 6800

When the image directory is accessed and thumbnail images are used to recall patient images, incorrect images may be displayed or there may be an inability to locate images on the system. The actual images, however, are labeled with the correct patient information, and may be located within another patient's file.

Interim Solution:

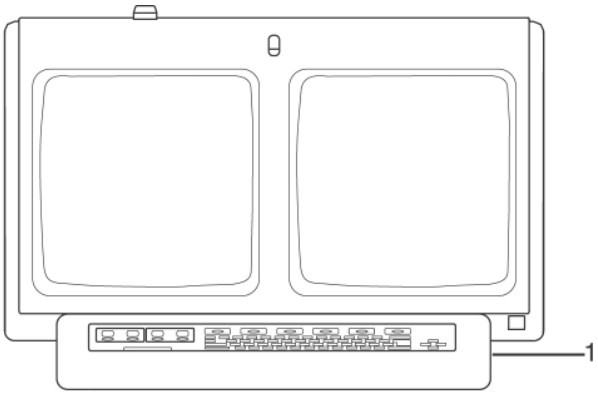
At this time a corrective software solution for the OEC 9800 Plus, OEC FlexiView 8800, OEC UroView 2800, and OEC MiniView 6800 is under investigation. Your facility will be notified as soon as a solution has been identified.

To reduce the occurrence of this issue users should follow the correct power down procedure.

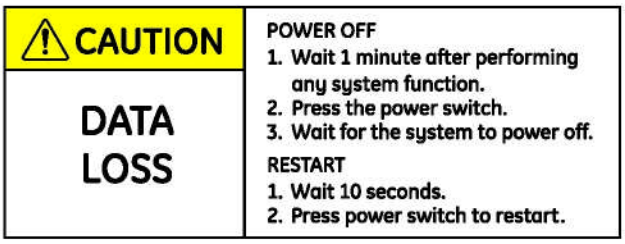
The power down procedure is also described in the Operators Guide and on the supplemental stickers enclosed with this notification.

The supplemental stickers should be installed on your system(s) promptly following the enclosed instructions and as indicated below (suggest placement in location #1).

Users are advised to exercise caution in using the system by verifying that the image displayed is consistent with current examination being reviewed and contains the correct patient demographic information on the image itself until a comprehensive and permanent solution has been developed.



SUGGESTED PLACEMENT OF STICKER ON SYSTEM


CAUTION
DATA LOSS
POWER OFF
1. Wait 1 minute after performing any system function.
2. Press the power switch.
3. Wait for the system to power off.
RESTART
1. Wait 10 seconds.
2. Press power switch to restart.

4. Incorrect Dose Area Product/Calculated Air Kerma in "Film Mode " and "Digital Spot Mode":

Affected Products: FlexiView 8800 Mobile C-Arm, OEC® UroView 2800OEC®, 9800OEC® FluoroTrak, 9800 PlusOEC®, 9800 Plus, OEC® 9800*MD* Motorized C-arm System

An issue has been reported that results in incorrect calculation, display and recording of patient dose while in film or digital spot mode. During a procedure, both the calculated Cumulative Air Kerma and the Air Kerma Rate can be observed on the live imaging monitor. This shows the AKR (air kerma rate) during fluoro exposures, and CAK (cumulative air kerma) after & between

fluoro acquisitions. Either during the procedure, or more typically, after the procedure, Cumulative Air Kerma and/or Dose Area Product (DAP is optional, depending on system configuration) can be viewed in a Dose Summary Screen, which can be invoked and displayed on the left monitor. This summary shows the total procedure CAK and DAP with a breakdown on what exposure modes were used, and what fractions of the total dose each mode was responsible for. In GE OEC systems, AKR is calculated from technique factors (kVp, mA, and if pulsing, the duty factor.) CAK is calculated from the same, but accumulated over the duration of the procedure. DAP is calculated from the same parameters and also the collimator opening area. The total dose listed on this screen will be incorrect only if the Film or Digital Spot are used during the relevant procedure. All other fluoroscopic modes correctly display the dose within current specifications (i.e. Fluoro, High Level Fluoro, Pulsed, Cine Record). This mis calculation could lead the clinicians to erroneously document the radiation exposure received by the patient

Interim Solution:

At this time a corrective solution for the FlexiView 8800 Mobile C-Arm, OEC® UroView 2800 OEC®, 9800OEC® FluoroTrak, 9800 PlusOEC®, 9800 Plus, OEC® 9800MD Motorized C-arm System is under investigation. Your facility will be notified as soon as a solution has been identified. In clinical scenarios in which an accurate record of the radiation exposure to the patient is required prior to the system receiving an upgrade, users should contact their GEHC OEC service provider for assistance in determining the actual radiation exposure.

5. System does not boot:

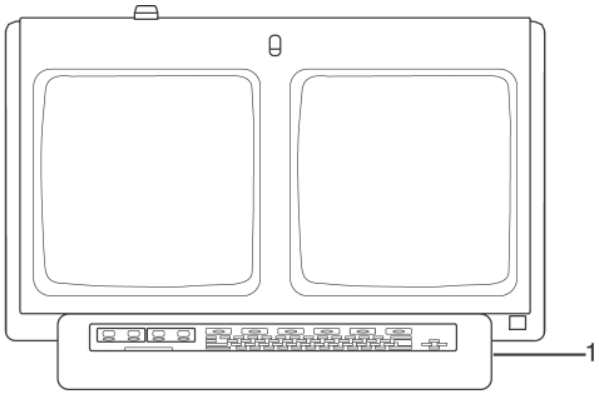
Affected Products: FlexiView 8800 Mobile C-Arm, OEC® UroView 2800, OEC® 9800, OEC® FluoroTrak 9800 Plus, OEC® 9800 Plus, OEC® 9800*MD* Motorized C-arm System, and OEC® Miniview 6800

FlexiView 8800 Mobile C-Arm, OEC® UroView 2800, OEC® 9800, OEC® FluoroTrak 9800 Plus, OEC® 9800 Plus, OEC® 9800MD Motorized C-arm System, and OEC® Miniview 6800 may stall during its boot cycle causing a delay in usage. If this condition persists for longer than a minute, the system is stalled.

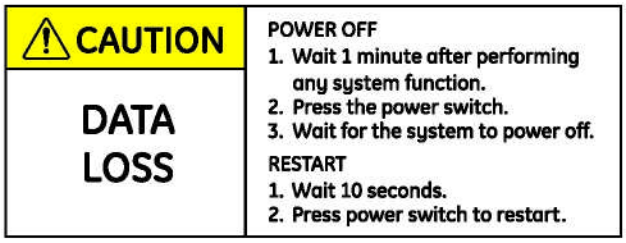
Interim Solution:

Rebooting the system should clear the issue and restore system functionality. When rebooting the system for this issue, before reapplying power, it is important to place the power switch in the OFF position and wait **10 seconds**. Should the system fail to reboot a second attempt at rebooting may be required. These instructions are located in the Operators Guide.

In addition enclosed is a sheet of supplemental stickers, including instructions for attachment that demonstrates the restart steps. These stickers should be promptly attached to your system(s) as indicated below (suggest placement in location #1).



SUGGESTED PLACEMENT OF STICKER ON SYSTEM


CAUTION
DATA LOSS
POWER OFF
1. Wait 1 minute after performing any system function.
2. Press the power switch.
3. Wait for the system to power off.
RESTART
1. Wait 10 seconds.
2. Press power switch to restart.

GEHC OEC is actively working on solutions that will permanently resolve each of these issues. When solutions become available for those issues that currently do not have a permanent solution, GEHC OEC will contact you and without charge, remedy these issues. For those issues that currently have a permanent fix identified, the GEHC OEC service team will be contacting you to install the correction shortly.

If you have any questions or concerns regarding these issues, please do not hesitate to contact the service team for further information at 800-874-7378 option 8. Information is available at this number 24 hours per day, 7 days a week.

Thank you,

Pete McCabe

Pete McCabe
President and CEO
GE Healthcare, Surgery
384 Wright Brothers Drive
Salt Lake City, Utah 84116
U.S.A.

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URGENT RECALL NOTICE

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVENT SYSTEM (S) OF THESE ISSUES AND HOW TO ADDRESS THEM

February 9, 2007

To: **Director/Manager of Radiology**

Subject: **Product Safety Issues**

Affected Products: **OEC® 9800, OEC® FluoroTrak 9800 Plus, OEC® 9800 Plus, OEC® 9800*MD* Motorized C-arm System,**

Our records indicate that your facility has one or more of the following GEHC OEC products:

- OEC® 9800
- OEC® FluoroTrak 9800 Plus
- OEC® 9800 Plus
- OEC® 9800*MD* Motorized C-arm System

GE Healthcare has identified a potential safety issue with the systems listed above that have the following serial numbers: **89-1685, 89-2907, 89-2877, 89-2383, 89-3330, 82-7059-MH, 89-0247-RC, 89-0599, and 89-2987, 89-1001, 89-0972**

According to our records, the systems with the serial numbers listed above had the camera cover on the Image Intensifier replaced during a service call. The camera shield that was placed onto your system during this service call may not have the protective lead barrier as required. The lack of lead shielding may result in excessive scatter radiation exposure to the user and patient and is non compliant with CFR 21 Sec. 1020.32.

At this time users are advised to stop using the systems with the corresponding serial numbers listed above until the camera cover and shields are inspected /replaced.

Solution:

GE OEC will be contacting your facility in the immediate future to schedule the replacement of the camera shield on your system with an appropriate protective lead barrier.

Users are advised to stop using the unit until the camera cover/shield has been inspected and replaced if necessary.

GEHC OEC is working on inspecting all affected systems and replacing all affected camera covers/shields as soon as possible at no charge to your facility.

If you have any questions or concerns regarding these issues, please do not hesitate to contact the service team for further information at 800-874-7378 option 8. Information is available at this number 24 hours per day, 7 days a week.

Thank you,

Pete McCabe
President and CEO
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384 Wright Brothers Drive
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URGENT RECALL NOTICE

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVENT SYSTEM (S) OF THESE ISSUES AND HOW TO ADDRESS THEM

February 28, 2007

To: **Director/Manager of Radiology**

Subject: **Product Safety Issues**

Affected Products: **OEC® 9800, OEC® FluoroTrak 9800 Plus, OEC® 9800 Plus, OEC® 9800MD Motorized C-arm System, OEC® 9900 Elite, OEC®, 9900 EliteMD Motorized C-arm System, OEC® 9900 EliteNAV, OEC® 8800 C-arm System**

Our records indicate that your facility has one or more of the following GEHC OEC products:

- OEC® 9800
- OEC® FluoroTrak 9800 Plus
- OEC® 9800 Plus
- OEC® 9800MD Motorized C-arm System
- OEC® 9900 Elite
- OEC® 9900 Elite*MD* Motorized C-arm System
- OEC® 9900 EliteNAV
- OEC® 8800 System

GE Healthcare Surgery has identified two (2) potential safety issues with the systems listed above that have had either the x ray tube and/or the collimator replaced.

If your facility is receiving this notification our records indicate that your OEC® 9800, OEC® FluoroTrak 9800 Plus, OEC® 9800 Plus, OEC® 9800MD Motorized C-arm System, OEC® 9900 Elite, OEC® 9900 EliteMD Motorized C-arm System, OEC® 9900 EliteNAV, OEC® 8800, System may be affected by one or both of these issues.

The possible improper replacement of either the collimator or x ray tube may have resulted in a compromising of the beam limiting provisions on your system, therefore a potential exists for less effective

stray radiation control measures which could result in additional unwanted x-ray exposure to the user and patient.

The system may be non compliant with 21 CFR Sec. 1020.32 with respect to the beam limiting, maximum entrance AKR (air kerma rate) requirements and leakage radiation provisions if one of the following situations exist:

- The primary collimator is missing and the system has not been properly calibrated
- The secondary collimator ring is missing and a collimator calibration has not been performed.

Internal testing by GEHC Surgery has determined that the standard service practices in place would most likely eliminate the occurrence of the two situations listed above. As a result, any non-compliance to 21 CFR 21 Sec. 1020.32 is unlikely and the product may continue to be used.

Solution:

GEHC Surgery is working on inspecting potentially affected systems and repaired them as appropriate as soon as possible at no charge to your facility. GEHC Surgery will be contacting your facility in the immediate future to schedule the inspection of your system.

If you have any questions or concerns regarding these issues, please do not hesitate to contact the service team for further information at 800-874-7378 option 8. Information is available at this number 24 hours per day, 7 days a week.

Thank you,

Pete McCabe
President and CEO
GE Healthcare, Surgery
384 Wright Brothers Drive
Salt Lake City, Utah 84116
U.S.A.

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PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVANT SYSTEM(S) OF THESE ISSUES AND HOW TO ADDRESS THEM

March 21, 2007

To:	**Director/Manager of Radiology** **Facility Administrator**
Subject:	**Product Safety Issues**
Affected Products:	**OEC® 9800, OEC® FluoroTrak 9800 Plus, OEC® 9800 Plus, and OEC® 9800MD Motorized C-arm System, OEC® 9900 Elite Fluoroscopy System, 9900 EliteMD Motorized C-arm System**

Our records indicate that your facility has one or more of the products listed above that are being used in conjunction with the four (4) pedal footswitch.

GE Healthcare has identified, through internal testing, the following potential safety issues that may occur with the four (4) pedal footswitch.

These issues include:

- Stalling on boot up.
- Grainy or washed out images
- "X-RAY SWITCH STUCK" error on boot up with and x-rays are not allowed.
- Image automatically saving if the footswitch is plugged in after system has booted.
- Saving during auto x-ray could cause the technique to go to maximum momentarily
- Mode button will not function.
- The third pedal takes an HLF shot instead of a Digital Cine shot and you could get an XRAY STUCK ERROR.

- Inability to take a Digital Cine shot
- Warning tone (beep) fails to activate

A GEHC Surgery field service engineer will be contacting your facility to remove the four (4) pedal footswitch and to install the appropriate 2 or 3 pedal footswitch.

Solution:

At this time GEHC Surgery will not be offering a replacement for the 4 pedal footswitch for use with the OEC® 9800, OEC® FluoroTrak 9800 Plus, OEC® 9800 Plus, and OEC® 9800MD Motorized C-arm System, OEC® 9900 Elite Fluoroscopy Systems, 9900 EliteMD Motorized C-arm System. Users will have the functionality previously available via the four (4) pedal footswitch by utilizing the 2 or 3 pedal footswitch combined with the hand switch.

If you have any questions or concerns regarding these issues, please do not hesitate to contact the service team for further information at 800-874-7378 option 8. Information is available at this number 24 hours per day, 7 days a week.

Thank you,

Pete McCabe
President and CEO

GE Healthcare

Pete McCabe
President and CEO
GE Healthcare, Surgery
384 Wright Brothers Drive
Salt Lake City, Utah 84116
U.S.A.
Pete.mccabe@med.ge.com

Certified Mail Return Receipt Requested

URGENT RECALL NOTICE

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVENT SYSTEM(S) OF THESE ISSUES AND HOW TO ADDRESS THEM

April 13, 2007

To: **Hospital Administrator**
Director/Manager of Radiology

Subject: **Product Safety Issues**

Affected Products: **OEC® 9900 Elite, OEC®, 9900 Elite*MD* Motorized C-arm System, OEC® OEC® 9900 Elite*NAV* , FlexiView 8800 Mobile C-Arm, OEC® Miniview 6800, OEC® UroView 2800, OEC® 9800, OEC® FluoroTrak 9800 Plus, OEC® 9800 Plus, OEC® 9800MD Motorized C-arm System**

Our records indicate that your facility has one or more of the following GEHC OEC products:

- OEC® 9900 Elite
- OEC® 9900 Elite*MD* Motorized C-arm System
- OEC® 9900 Elite*NAV*
- FlexiView 8800 Mobile C-Arm
- OEC® Miniview 6800
- OEC® UroView 2800
- OEC® 9800
- OEC® FluoroTrak 9800 Plus
- OEC® 9800 Plus
- OEC® 9800*MD* Motorized C-arm System

GE Healthcare previously identified and communicated intermittent potential safety issues that may occur with the products listed above. The details and symptoms of these issues, as well as the associated interim solutions, were described in the Recall Notification dated November 8, 2006. **As the result of the investigation of a reported incident, we are updating item 3 of that notification as follows:**

Incorrect Image Display:

Affected Products: OEC® 9900 Elite, OEC®, 9900 Elite*MD* Motorized C-arm System, OEC® OEC® 9900 Elite*NAV* , FlexiView 8800 Mobile C-Arm, OEC® Miniview 6800, OEC® UroView 2800, OEC® 9800, OEC® FluoroTrak 9800 Plus, OEC® 9800 Plus, OEC® 9800MD Motorized C-arm System

When the image directory is accessed and thumbnail images are used to recall patient images, incorrect images may be displayed or there may be an inability to locate images on the system. The actual images may display **incorrect** patient information and may be located within another patient's file.

Interim Solution:

Solutions to eliminate this issue are under investigation by GEHC OEC. To reduce the occurrence of this issue, users should follow the correct power down procedure. The power down procedure is described in the Operators Guide and on the supplemental stickers previously sent to your facility in November 2006.

Users are advised to exercise caution in using the system by verifying that the image displayed is consistent with current examination and patient being reviewed until a comprehensive and permanent solution has been developed.

GEHC OEC is actively working on solutions that will permanently resolve this issue. When a solution becomes available GEHC OEC will contact you and without charge, remedy this issue.

If you have any questions or concerns regarding these issues, please do not hesitate to contact the service team for further information at 800-874-7378 option 8. Information is available at this number 24 hours per day, 7 days a week.

Thank you,

Pete McCabe
President and CEO

GE Healthcare

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Important Electronic Product Radiation Warning

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVANT SYSTEM(S) OF THESE ISSUES AND HOW TO ADDRESS THEM

April 2, 2007

To:	**Hospital Administrator**
	Director/Manager of Radiology
Subject:	**Product Safety Issues**
Affected Products:	**OEC® 9900 Elite** **OEC® 9800** **OEC® 8800** **OEC® 6800** **OEC® 2800**

Our records indicate that your facility has one or more of the products listed above.

GE Healthcare has identified an issue affecting the OEC® 9900 Elite, OEC® 9800, OEC® 8800, OEC® 6800, OEC® 2800.

A configuration issue has been discovered that results in the failure of the above listed systems to display the US Standard quantity air kerma as required to describe the radiation output for systems manufactured after June 10, 2006 by 21 CFR 1020.32(k).

For the 9800, 8800, 6800 and 2800 products the Air Kerma and DAP can both be displayed at the same time if properly configured. If not configured correctly, these products will only show the DAP calculation. The 9900 product can only display one value or the other. When the 9900 system is incorrectly configured Air Kerma is not displayed, however, the DAP is.

This issue does not affect the safe operation of your system, however, it does result in your system not being in compliance with 21 CFR 1020.32(k).

Your GEHC OEC service representative will be contacting you in the near future to arrange for an inspection to determine if the issue affects your system and will correct the configuration settings if needed at that time at no charge.

If you have any questions or concerns regarding these issues, please do not hesitate to contact the GEHC OEC service team for further information at 800-874-7378 option 8. Information is available at this number 24 hours per day, 7 days a week.

Thank you,

Pete McCabe
President and CEO

IMPORTANT DEVICE CORRECTION INFORMATION

GE Healthcare Product Safety Alert

xx June 2005

Dear Healthcare Professional:

GE Healthcare's records indicate that the following accessory used with your surgical navigation system(s) has been distributed to your healthcare facility:

Picture	Description	Catalog Part Number	Number printed on Cable
	Extended Range Transmitter	1004070 or 1003991	1003804 or 1001221

Please note that for the remainder of this letter, the above listed accessory will be referred to as "Sensor".

The Sensor is provided for use with the ENTrak Plus, InstaTrak 3000, InstaTrak 3500, InstaTrak 3500 Plus, and GE OEC FluoroTrak Navigation and Visualization systems. These systems may also be commonly known as the "VTI" system from Visualization Technologies, Inc. Please be advised that we have identified a potential safety concern associated with this Sensor. Due to a problem in the manufacturing process, the Sensor may not meet an electrical requirement of the IEC 60601-1 standard, which qualifies the system for a Nationally Recognized Test Lab (NRTL) mark, "CSA" or "ETL". These are displayed on the rear, near the rating label.

Our testing revealed there might be a risk of patient shock under certain circumstances due to a potential failure in the Sensor housing. Please note that patient health would only be at risk if other subsystem failures occurred in conjunction with the housing failure. As of this date, there have been no reports of any patient shocks resulting from the use of the Sensor; this issue was discovered by engineering tests in our labs.

We believe that using surgical navigation equipment is more of a benefit to public health than the potential risk of injury due to this issue. Therefore, we recommend that you continue to use your GE OEC Surgical Navigation System until we can replace the affected Sensor. Based upon the article "Comparison of endoscopic sinus surgery (ESS) with and without image guidance" By Fried et. al. in the American Journal of Rhinology 2002;16(4):193-197, 11% of patients encounter a major complication if the procedure is not navigated versus 1% if a procedure uses navigation. The foreseeable risk of any shock event while using the Sensor is less than x%, at least ten thousand times lower than the risk of a major complication while using navigation.

We ask you to please contact us to arrange for replacement of your Sensor. GE appreciates your awareness and cooperation in order to remedy this potential health concern. To obtain a replacement Sensor and if you have any questions, please contact GE Healthcare Customer Service at (800) 874-7378 and select Option 1.

Sincerely,

Gary Harding
VP, Regulatory/Six Sigma

GE Healthcare

Pete McCabe
President and CEO
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384 Wright Brothers Drive
Salt Lake City, Utah 84116
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Important Electronic Product Radiation Warning

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVANT SYSTEM(S) OF THESE ISSUES AND HOW TO ADDRESS THEM

June 12, 2007

To:	**Hospital Administrator**
	Director/Manager of Radiology
Subject:	**Product Safety Issues**
Affected Products:	**OEC ® 9900 Elite** **OEC ® 9800** **OEC ® 8800** **OEC ® 6800** **OEC ® 2800**

Our records indicate that your facility currently has one or more of the products listed above.

GE Healthcare has identified an issue affecting these products as described below. This communication is intended to provide clarification on the prior communication dated April 2, 2007.

Failure to display Air Kerma and Cumulative Air Kerma:

A configuration issue has been discovered that results in the failure of the system to display the International Standard quantity, air kerma, to describe the radiation output. The usage of Air Kerma to replace entrance exposure, and the display of Air Kerma Rate and Cumulative Air Kerma are required on systems manufactured after June 10, 2006 by 21 CFR 1020.32(k). In GE OEC systems, AKR (air kerma rate) is calculated from technique factors (kVp, mA, and if pulsing, the duty factor.) CAK (cumulative air kerma) is calculated from the same, but accumulated over the duration of the procedure.

These systems, as shipped, did not meet the requirement of 21 CFR 1020.32(k), in that the systems were not configured to display Air Kerma Rate and Cumulative Air Kerma at the operators working position on individually distinguishable displays.

This issue does not impact the safety of operation of your system, however does result in non-compliance to 21CFR 1020.32 (k).

Your GEHC Surgery service representative will be contacting you in the near future to arrange for an inspection and to modify your system configuration if necessary to assure compliance with the requirements of 21 CFR 1020.32(k) at no charge.

If you have any questions or concerns regarding these issues, please do not hesitate to contact the GEHC OEC service team for further information at 800-874-7378 option 8. Information is available at this number 24 hours per day, 7 days a week.

Thank you,

Pete McCabe
President and CEO

GE Healthcare

GE Healthcare, Surgery
384 Wright Brothers Drive
Salt Lake City, Utah 84116

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URGENT RECALL NOTICE

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVANT SYSTEM(S) OF THESE ISSUES AND HOW TO ADDRESS THEM

January 10, 2008

To: **Hospital Administrator**
Director/Manager of Radiology

Subject: **Product Safety Issues:**
Vertical Lift Column Failure (PS3 Power Supply failure)

Affected Products: **OEC® 9900 Elite, OEC®, 9900 Elite*MD* Motorized C-arm System, OEC® 9900 Elite*NAV* , OEC® 9800, OEC® FluoroTrak 9800 Plus, OEC® 9800 Plus, OEC® 9800MD Motorized C-arm System, OEC® 8800 Flexiview**

Our records indicate that your facility has one or more of the following GEHC OEC products:

- OEC® 9900 Elite
- OEC® 9900 Elite*MD* Motorized C-arm System
- OEC® 9900 Elite*NAV*
- OEC® 9800
- OEC® FluoroTrak 9800 Plus
- OEC® 9800 Plus
- OEC® 9800***MD*** Motorized C-arm System
- OEC® 8800 Flexiview

GE Healthcare has received reports from some customers of the vertical lift function of the C portion of the device failing on the above listed products. Failure of this functionality could result in the user experiencing difficulty in positioning the device.

Interim Solution:

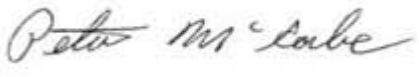
To reduce the potential occurrence of this issue, users are advised to avoid activating both the up and down directional movement buttons on the mainframe at the same time. Should the user note that the vertical lift is slow to respond, or intermittently fails to respond to an up or down command, the user should contact the OEC Service Department at GEHC Surgery for a replacement of the failing power supply (PS3).

In addition, users should verify that the standby key switch is in the full ON position prior to attempting to use the vertical lift feature, as this was also identified as a potential cause for vertical lift column failure.

GEHC OEC is actively working on a solution that will permanently resolve this issue. When a solution becomes available GEHC OEC will contact you and at no cost resolve this issue.

If you have any questions or concerns regarding this issue, please do not hesitate to contact the service team for further information at 800-874-7378 option #8. Information is available at this number 24 hours per day, 7 days a week.

Thank you,



Pete McCabe
President and CEO

Maria Frame
Vice President Quality and Regulatory Affairs